	-		ı		
ATTACHMENT		Page 2 of 2			
	son and Company				
	alculations for SIP Application (Actual)				
Facility:					
Input data:					
Ethylene oxide u	Isage	390,400	lb/vr	Total usage based on Mass Balance (CY 2018)	
Sterilizer remov	-	99.9%	,	Based on partial pressure calculation estimate	
RTO efficiency, a		99.970%		Based on 2019 Performance Testing	
RTO efficiency, v		99.999%		Based on 2019 Performance Testing	
Product transfer time, sterilizer to aeration			min	based on 2015 renormance resumg	
Aeration time			hr		
	Latina a	1	min		
Aeration Unload		1	min		
System 1 remov	•	99%		Assume 99% Based on vendor literature	
System 2 remov	al efficiency	99%		Assume 99% Based on vendor literature	
				Safety factor included to account for variation in future products and product	
System 2 Safety	Factor	4.00		density which may impact EO residuals.	
Assumptions:					
Product absorpt	ion <sup>2</sup>	0.4%			
EO degassing rat		0.06151	lh/hr		
Miscellaneous fu		100		captured in system 1	
IVII3CEIIAITEOU3 II	I I I I I I I I I I I I I I I I I I I	100	IU	captured in system 1	
Calculations:					
Sterilizer:					
EO into sterilize		390,300		Total usage based on Mass Balance minus miscellaneous fugitive loss	
EO absorbed by		1,561.2			
	ot absorbed by product	388,738.8			
	RTO from vac/air wash	388,350.1			
EO exhausted to		388.7			
Sterilizer exhaus	st to RTO	388,738.8	lb		
Sterilizer exhaus	t removed by RTO	388,734.9			
	st to atmosphere after RTO	3.9			
Transfer:					
	•			EO will off-gas from products during aeration per equation: $C = C_0 e^{(-kt)}$ , where $C = C_0 e^{(-kt)}$	
				Final EO concentration, $C_0 = EO$ concentration at time 0, $k = EO$ degassing rate	
EO offgag durin	nroduct transfer to poration	0.51%			
	g product transfer to aeration			constant, and t = degassing time in hrs.	
	product transfer to aeration	8.0	al	This will be captured by system one	
Aeration:					
	product entering aeration	1,553.2	lb		
Offgas during ac		62.6%			
Offgas during ur		1.0%			
EO offgas during		972.7			
To RTO during a		972.7			
To RTO during a		5.9			
Total aeration to		978.6			
Aeration remove	ed by RTO	978.3			
Aeration exhaus	t to atmosphere after RTO	0.3	lb		
System1:					
Into System 1		108.0	lb		
Removed by Sys		106.9	lb		
System 1 exhaus	st to atmosphere	1.1			
System2:					
Into System 2		2,298.4	lb	Includes System 2 Safety Factor	
Removed by Sys	tem 2	2,275.4	lb		
System 2 exhaus	st to atmosphere	23.0			
Exhausted befor	e Modification:				
EO exhausted to	atmosphere from RTO	4.2	lb		
	atmosphere by system 1	108.0			
	to atmosphere System 2	574.6	lb	Does not Includes System 2 Safety Factor <sup>5</sup>	
	sted to atmosphere	686.8		Before Modifications	
. C.C. LO CANADA			Tons		
		0.5			
Exhausted after	Modification:	<b>†</b>			
	atmosphere from RTO	4.2	lb		
	atmosphere by system 1	1.1			
	to atmosphere System 2	23.0		Includes System 2 Safety Factor	
	sted to atmosphere	28.2		morades system 2 surety ructor	
TOTAL EO EXIIDUS	To a uniospinere		Tons	After Modifications	
<b></b>		0.014	10113	ATTEN INCUMENTALIS	
Note 1				l	
	This estimates how much EO is removed during post exposure vacuum washes but does not include what is in the product at the time it transfers to Aeration				
Note 2	Estimates the amount of EO in the product when it starts the transfer to aeration				
Note 3	An estimate based on Product EO Residue Testing performed by BD laboratory personnel.				
Note 4	An estimate of potential EO emissions from pump/va				
				the new System is designed to account for variation in future products and	
Note 5		acion calculatio	מות as uns insures	the new System is designed to account for variation in future products and	
Note 5	product density which may impact EO residuals.	1	ı		
<b>—</b>		<b> </b>			
<u> </u>		1			
<u> </u>		-			
<u> </u>		1			
<u> </u>		1			
		1			
		ļ			
1		ļ			
		<u> </u>			
			1		